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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,345	03/18/2004	Rae Ellen Syverson	KCC 4749.2 (K-C 16,858.2)	5820
321	7590	05/17/2006	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			CHANNAVAJJALA, LAKSHMI SARADA	
			ART UNIT	PAPER NUMBER
			1615	

DATE MAILED: 05/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/803,345

Applicant(s)

SYVERSON ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-68 is/are pending in the application.
- 4a) Of the above claim(s) 2-10, 12, 13 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 11, 14-20 and 22-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1-23-06; 1-27-06, 8-18-05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment and remarks dated 2-27-06 is acknowledged.

Claims 1-68 are present in the case. Claims 1, 11, 14-20 and 22-68 are considered for examination. Claims 2-10, 12, 13 and 21 are withdrawn from consideration.

Response to Arguments

Response to Arguments

Applicants' arguments filed 2-27-06 have been considered but not found persuasive. The following rejections of record have been maintained:

Claim Rejections - 35 USC § 103

1. Claims 1, 11 and 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over DE 1204777 in view of US 6,416,779 to D'Augustine.

A complete rejection under this section can be found in the previous action.

RESPONSE: Applicants argue that DE teaches benzamide to increase the bactericidal activity of hexachlorophene by adding 50% to 91% by weight of hexachlorophene to increase the activity against *S. aureus* by 37% to 100%. It is argued that DE fails to teach non-absorbent substrates of the instant claims, for insertion in to vagina.

However, the instant rejection is made over a combination of references and the teaching of D'Augustine has been relied upon for the claimed non-absorbent materials.

Applicants argue that the combination of the teachings of D'Augustine i.e., the use of vaginal devices and antibacterial, antifungal or antiviral composition for treating vaginal infections, does not meet the requirements for establishing prima facie

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obviousness, without the blue print of applicants' disclosure. Applicants argue that the motivation to combine the above references is not convincing as to why one skilled in the art would pick the composition of DE over all of the other toxic, antibacterial compositions of the art, when D'Augustine describes numerous suitable antibacterial compositions to use with their non-absorbent devices. Applicants arguments are not persuasive because DE suggests a synergistic increase in the antibacterial activity by the addition of compounds such as benzamide, aniline etc., which is a very small group of group of compounds as opposed to the argument that DE suggests numerous other compounds. On the other hand D'Augustine teaches antibacterial compounds but does not teach the highly synergistic effect in treating bacterial infection, which is suggested by DE. Applicants' argument that DE is silent about the use of benzamide on intra-vaginal devices is not persuasive because the motivation to employ the benzamide on the claimed devices comes from the teaching of D'Augustine, which describes several bacterial infections that occur in vaginal area.

Applicants argue that while DE recognizes benzamide as a antibacterial agent, the first active ingredient of the instant claims is an used as an exoprotein inhibitor and not an antibacterial agent without seeking to kill the bacterial as the killing is non-selective that includes killing good bacteria in the vaginal area and is thus harmful. Applicants' arguments are not persuasive because instant claims do not exclude killing of the bacteria while inhibiting exoprotein inhibition. Instant claims also fail to recite the limitation that the "good" bacteria should not be killed. Further, even though the references cited recognize antibacterial effect, it is to be noted that the while the

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ultimate effect of an antibacterial agent is killing the bacteria, such an effect includes inhibiting proteins. Thus, the antibacterial teaching of DE is inclusive of inhibiting exoprotein.

2. Claims 1, 11, 14-20, 22-31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,612,045 ('045) in view of DE 1204777 (DE).

A complete rejection under this section can be found in the previous action.

RESPONSE: Applicants present the same arguments with respect to the teachings of DE. Applicants argue that the office failed to meet its burden to establish prima facie case of obviousness. It is argued that the cited references do not teach the non-absorbent substrate claimed, and that '045 is directed to employing ether compounds that can be used with absorbent articles such as catamenial tampons to inhibit the exoprotein of Gram positive bacteria, more specifically to solve the problem of TSST-1 produced by *S. aureus*. It is argued that '045 do not teach benzamide and that DE does not teach that benzamide can be used safely for humans. Applicants' arguments are not persuasive because the motivation to use benzamide of DE in the intra-vaginal devices comes from the teachings of '045, which also teaches infections and the toxic conditions caused by the same organism *S. aureus*. '045 further teaches that the compounds effective against *S. aureus* can be used in combination with compounds such as ether be used on absorbent as well as non-absorbent fibers of the devices, such as covers or wrappers of the vaginal devices including tampons (col. 3, lines 55-60). Thus, '045 clearly suggest a rationale for employing compounds effective against *S. aureus* on

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absorbent as well as non-absorbent articles. If applicants' argument that benzamide would unavoidably and inevitably could harm the sensitive mucosal membrane of inner vagina, then the same argument should hold true for the claimed invention because instant invention also employs the same benzamide. Accordingly, the argument is moot.

3. Claims 1, 11, 14-20 and 48-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,685,872 ('872) in view of DE 1204777 (DE).

A complete rejection under this section can be found in the previous action.

RESPONSE: Applicants present same arguments with respect to the teachings of DE.

Applicants argue that the office failed to meet its burden to establish prima facie case of obviousness. It is argued that the cited references do not teach the non-absorbent substrate claimed, and that '872 is directed to employing compounds that can be used with absorbent articles such as catamenial tampons to inhibit the exoprotein of Gram positive bacteria, particularly for toxic shock syndrome caused by *S. aureus*. It is argued that '872 do not teach benzamide or using the compounds on non-absorbent articles as claimed, and that DE does not teach that benzamide can be used safely for humans.

Applicants' arguments are not persuasive because the motivation to use benzamide of DE in the intra-vaginal devices comes from the teachings of '872, which also teaches infections and the toxic conditions caused by the same organism *S. aureus*. '872 further teaches that the compounds effective against *S. aureus* can be used in combination with compounds such as ether be used on absorbent as well as non-absorbent fibers of the devices, such as covers or wrappers of the vaginal devices including tampons

(paragraph bridging col. 3 and col.4). Thus, '872 clearly suggest a rationale for employing compounds effective against *S. aureus* on absorbent as well as non-absorbent articles. If applicants' argument that benzamide would unavoidably and inevitably could harm the sensitive mucosal membrane of inner vagina, then the same argument should hold true for the claimed invention because instant invention also employs the same benzamide. Accordingly, the argument is moot.

4. Claims 56-62 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,618,554 ('554) in view of DE 1204777 (DE).

A complete rejection under this section can be found in the previous action.

RESPONSE: Applicants present same arguments with respect to the teachings of DE. It is argued that DE fails to teach second active agent or the non-absorbent device of the instant claims. Applicants argue that the office failed to meet its burden to establish prima facie case of obviousness. It is argued that the cited references do not teach the non-absorbent substrate claimed, and that '554 is directed to employing nitrogen containing compounds that can be used with absorbent articles such as catamenial tampons to inhibit the exoprotein of Gram positive bacteria, more specifically to solve the problem of TSST-1 produced by *S. aureus*. It is argued that '554 do not teach benzamide and that DE does not teach that benzamide can be used safely for humans. Applicants' arguments are not persuasive because the motivation to use benzamide of DE in the intra-vaginal devices comes from the teachings of '554, which also teaches infections and the toxic conditions caused by the same organism *S. aureus*. '554 further

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teaches that the compounds effective against *S. aureus* can be used in combination with compounds such as ether be used on absorbent as well as non-absorbent fibers of the devices, such as covers or wrappers of the vaginal devices including tampons. Thus, '554 clearly suggest a rationale for employing compounds effective against *S. aureus* on absorbent as well as non-absorbent articles. If applicants' argument that benzamide would unavoidably and inevitably could harm the sensitive mucosal membrane of inner vagina, then the same argument should hold true for the claimed invention because instant invention also employs the same benzamide. Accordingly, the argument is moot.

The following is a new rejection:

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 11, 14-20 and 22-68 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S.

Patent 6,821,999 in view of any one of US 5,612,045 ('045), US 5,685,872 ('872) or US 5,618,554 ('554). Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims directed to a method of inhibiting the production of TSST-1 from Gram positive bacteria located in and around the vagina by exposing the vaginal bacteria to a vaginal cleansing formulation comprising thiomolactone and a second active ingredient comprising the general formula (II) that includes the first active compounds of the instant claims. Thus, the patented claims employ the compounds of the instant claims for the same purpose i.e., exoprotein inhibition, as that claimed. While the patented claims fails to recite the claimed non-absorbent device, each of '554, '045 or '872 teach the compounds of patented claim 2 as exoprotein inhibitors coated on absorbent or non-absorbent intra-vaginal devices such as catamenial tampons. Therefore, it would have been obvious for one of ordinary skill in the art at the time of the instant invention to use the compounds of formula II alone or in combination with exoprotein inhibiting compounds such as those recited in claim 2 of the patent together with non-absorbent vaginal devices for inhibiting exoprotein production by Gram positive bacteria in the vaginal area because the patented claims teach these compounds as effective for the same purpose and further all of '554, '045 and '872 teach applying the exoprotein inhibitor compounds on absorbent articles as well as non-absorbent articles that hold absorbent articles so as to successfully deliver the compounds to the vaginal area. Further, optimizing the amounts of each of the active agents so as to achieve complete inhibition of exoprotein would have been within the scope of skilled artisan.


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No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
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May 12, 2006